

Notice of Allowability

Application No.

09/840,722

Examiner

Frank W. Lu

Applicant(s)

MACLEOD ET AL.

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 4/10/2007.
2. ☒ The allowed claim(s) is/are 3, 4, 20, 21, 23-29, 36-42, 44-48, 50, 52-76, 85, and 86.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
- * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☒ Interview Summary (PTO-413),
Paper No./Mail Date 6/2007
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____

DETAILED ACTION

EXAMINER'S AMENDMENTS

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Mr. Steve Highlander (Reg. No. 37,642) on June 19, 2007 and a telephone interview with Mr. David Parker (Reg. No. 32,165) on August 24, 2006.

2. The application has been amended as follows:

In the specification:

Replace page 14, lines 13 through 20 with the following paragraph:

FIG. 4. Tactics for competitive RT-PCRTM with [COP] RAGE primers. The portion of the HSP27 cDNA sequence (SEQ ID NO:4) indicated with the heavy underline below can be amplified by the standard primers [COP] RAGE 32 (SEQ ID NO:3) and [COP] RAGE 46 (SEQ ID NO:5). Primer CRT004, containing the [COP] RAGE 32 sequence, a 5 bp insert (identified by the box), and the next 8 bp from HSP27 ("clamp" sequence, identified by overline) were synthesized. When CRT004 (SEQ ID NO:6) and [COP] RAGE 46 were used in a PCRTM reaction containing the HSP27 template, an amplicon identified as CRT32/46 (SEQ ID NO:7) was produced. As CRT32/46 contains all of the HSP27 sequences plus the 5 bp insert it can be used as a competitive template.

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Replace page 15, lines 14 through 21 with the following paragraph:

FIG. 8. Partial sequence of MLN 62 mRNA (SEQ ID NO:8). Primers for COP are highlighted, and the poly(A) addition signal sequence is underlined. The A-end primer sequence (CATGCCTT), starting at position 1760, contains the CATG that is closest to the 3' end of the mRNA. The highlighted B-end primer sequence (TGAGATC), starting at position 1880, contains the first GATC following the A-end primer. Note that the actual B-end primer contains the reverse complement of the highlighted sequence (GATCTCA). This decreases the number of positions queried at the B-end by one, thus reducing the number of experiments by a factor of four.

In the claims:

Replace "random sequences" in line 16 in ii) of step b) of claim 20 with "random combinations".

38. (Currently amended) The method of claim 36, further comprising determining [at least] a [partial] nucleotide sequence of the amplified products.

60. (Currently amended) The method of claim 20, [performed on] the DNA molecule is derived from a normal cell or tissue [and on] or DNA derived from a different cell or tissue.

61. (Currently amended) The method of claim 20, [performed on] the DNA molecule is derived from a normal cell or tissue [and on] or DNA derived from a cancerous cell or tissue.

62. (Currently amended) The method of claim 20, [performed on] the DNA molecule is derived from a normal cell or tissue [and on] or DNA derived from a cell or tissue treated with a pharmaceutical compound.

63. (Currently amended) The method of claim 20, [performed on] the DNA molecule is

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derived from a normal cell or tissue [and on] or DNA derived from a cell or tissue treated with a teratogenic compound.

64. (Currently amended) The method of claim 20, [performed on] the DNA molecule is derived from a normal cell or tissue [and on] or DNA derived from a cell or tissue treated with a carcinogenic compound.

65. (Currently amended) The method of claim 20, [performed on] the DNA molecule is derived from a normal cell or tissue [and on] or DNA derived from a cell or tissue treated with a toxic compound.

66. (Currently amended) The method of claim 20, [performed on] the DNA molecule is derived from a normal cell or tissue [and on] or DNA derived from a cell or tissue treated with a biological response modifier.

67. (Currently amended) The method of claim 20, [performed on] the DNA molecule is derived from a normal cell or tissue [and on] or DNA derived from a cell or tissue treated with a hormone, a hormone agonist or a hormone antagonist.

68. (Currently amended) The method of claim 20, [performed on] the DNA molecule is derived from a normal cell or tissue [and on] or DNA derived from a cell or tissue treated with a cytokine.

69. (Currently amended) The method of claim 20, [performed on] the DNA molecule is derived from a normal cell or tissue [and on] or DNA derived from a cell or tissue treated with a growth factor.

70. (Currently amended) The method of claim 20, [performed on] the DNA molecule is derived from a normal cell or tissue [and on] or the DNA derived from a cell or tissue treated

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with the ligand of a known biological receptor.

71. (Currently amended) The method of claim 20, [performed on] more than one sample of DNA are used, wherein the DNA samples are derived from a cell or tissue type obtained from different species.

72. (Currently amended) The method of claim 20, [performed on] more than one sample of DNA are used, wherein the DNA samples are derived from a cell or tissue type obtained from different organisms.

73. (Currently amended) The method of claim 20, [performed on] more than one sample of DNA are used, wherein the DNA samples are derived from a cell or tissue at different stages of development.

74. (Currently amended) The method of claim 20, [performed on] more than one sample of DNA are used, wherein the DNA samples are derived from a normal cell or tissue and derived from a cell or tissue that is diseased.

75. (Currently amended) The method of claim 20, [performed on] more than one sample of DNA are used, wherein the DNA samples are derived from a cell or tissue cultured [in vitro] in vitro under different conditions.

76. (Currently amended) The method of claim 20, [performed on] the DNA molecule is derived from a cell or tissue from two organisms of the same species with a known genetic difference.

3. The following is an examiner's statement of reasons for allowance:

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Claims 3, 4, 20, 21, 23-42, 44-48, 50, 52-76, 85, and 86 are allowable in light of applicant's amendments filed on June 20, 2006, and the examiner's amendments. The closest prior art in the record is Senapathy (US Patent No. 6,521,428 B1, priority date: April 21, 1999). This prior art does not teach that the 5' sequence of primers of said first primer set population is complementary to said first linker sequence and 5' sequence of primers of said second primer set population is complementary to said second linker sequence as recited in claim 20. This prior art either alone or in combination with the other art in the record does not teach or reasonably suggest a method of subjecting a DNA molecule to a DNA synthesis reaction which comprises all of the limitations recited in claim 20. Note that "a random combinations of A, T, C, and G" in amended claim 20 is considered as all possible combinations of A, T, C, and G.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

4. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is (571)273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (571)272-0746. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571)272-0735.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

June 20, 2007



FRANK LU
PRIMARY EXAMINER